



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------------------------|
| 10/073,522 | 02/11/2002 | Cristian L. Achim | 214001-00823-1 | 5288 |
| 7590 | 12/03/2003 | | | EXAMINER NICHOLS, CHRISTOPHER J |
| | | | | ART UNIT 1647 PAPER NUMBER |
| | | | | DATE MAILED: 12/03/2003 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/073,522 | ACHIM ET AL. |
| | Examiner Christopher Nichols, Ph.D. | Art Unit 1647 |

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 October 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 3,7-13,16 and 18-28 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-6,14,15,17 and 29-36 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11 February 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s) _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 16 October 2003 has been received and entered in full. Claims 1, 2, 5, 6, 14, and 15 have been amended. Claims 29-36 have been added. Claims 3, 7-13, 16, and 18-28 remain withdrawn from consideration.

Withdrawn Objections And/Or Rejections

2. The Objection to the Specification as set forth at pp. 3 ¶5 in the previous Office Action (25 April 2003) is *withdrawn* in view of Applicant's amendments (16 October 2003).

3. The Objection to the Oath/Declaration as set forth at pp. 3 ¶4 in the previous Office Action (25 April 2003) is *withdrawn* in view of the submission of an updated Application Data Sheet (MPEP §601.05).

4. The Rejection of claims **1, 2, 4-6, 15, 15**, and **17** under 35 U.S.C. §103(a) as set forth at pp. 9-11 ¶19-26 in the previous Office Action (25 April 2003) is *withdrawn* in view of Applicant's amendments (16 October 2003).

5. The Rejection of claims **5** and **6** under 35 U.S.C. §112 ¶2 as set forth at pp. 8 ¶16 in the previous Office Action (25 April 2003) is *withdrawn* in view of Applicant's amendments (16 October 2003).

6. The Rejection of claims **2** and **15** under 35 U.S.C. §112 ¶2 as set forth at pp. 8 ¶17 in the previous Office Action (25 April 2003) is *withdrawn* in view of Applicant's amendments (16 October 2003).

Maintained Objections And/Or Rejections

7. Claims 1, 2, 4-6, 14, 15, 17, and 29-36 are rejected under 35 U.S.C. §112 ¶1, because the specification, while being enabling for *a method for treating a neurodegenerative illness of the central nervous system in a patient comprising culturing neuronal cells in vitro with an effective amount of FK506 or cyclosporin A; and transplanting said cultured neuronal cells into said patient wherein the neurodegenerative illness of the central nervous system selected from the group consisting of Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, Alzheimer's disease, or ischemic cerebral stroke, does not reasonably provide enablement for compounds having an affinity for immunophilins (other than FK506, or cyclosporin A), rapamycin, FK520, FK-523, 15-O-DeMe-FK-520, (4R)-[(E)-L-butenyl]-4,N-dimethyl-L-theronin, or biological equivalents thereof or other neurodegenerative illnesses*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims for the reasons set forth at pp. 3-8 ¶6-15 in the previous Office Action (25 April 2003).

8. The Applicant traverses this rejection on the following grounds: (a) the use of compounds other than FK506 or cyclosporin A is taught by the specification, (b) the specification taken with US 6140116 and Fricker-Gates *et al.* (2001) "Neural Transplantation: Restoring Complex Circuitry in the Striatum." Restorative Neurology and Neuroscience 19(2-3): 119-138 provide sufficient guidance to practice the invention as claimed, (c) (d) (e) (f).

9. On "(a)", the argument provided by the Applicant constitutes an invitation to experiment. Since no guidance is provided by the specification and prior art other trial and error, this does not constitute an enabling disclosure. To determine if any given compounds fits into the rubric as

broadly claimed and has the desired effect, a skilled artisan must practice both *in vitro* screening assays as well as animal models thus representing an undue burden of experimentation.

10. On "(b)", the argument provided by the Applicant constitutes an invitation to experiment. Since no guidance is provided by the specification and prior art other trial and error, this does not constitute an enabling disclosure. In fact, both 6140116 and Fricker-Gates *et al.* (2001) "Neural Transplantation: Restoring Complex Circuitry in the Striatum." Restorative Neurology and Neuroscience 19(2-3): 119-138 provide obstacles and discuss the difficulties in practicing cell transplantation therapy. As taught by these references, cell transplantation therapy is notoriously difficult and unpredictable and for the skilled artisan to determine if any given central nervous system illness can be remedied by practicing the invention as broadly claimed, a skilled artisan must practice both *in vitro* assays as well as animal models thus representing an undue burden of experimentation in a difficult and unpredictable field.

11. The rejection of claims 1, 2, 4-6, 14, 15, 17, and 29-36 under 35 U.S.C. §112 ¶1 is hereby maintained.

12. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth at pp. 8 ¶18 of the previous Office Action (25 April 2003).

13. The Applicant traverses this rejection on the following grounds that page 7 of the specification provides adequate definition for the term "biological equivalents".

14. The Applicant's argument has been taken into consideration and is not found persuasive for the following reasons. The specification only provides a general, prophetic concept of what a "biological equivalent" may be. No examples are given, nor any conserved structure, necessary properties, nor clear metes and bounds are provided to define the term "biological equivalents". Thus it may pertain to any chemical entity, pharmaceutical composition, protein, peptide, non-peptide compound, animal tissue extract, vegetable extract, cell extract, synthetic agent, biologically derived substance as well as proteinaceous substance, known, and unknown compounds. Hence the skilled artisan is not sufficiently apprised of the metes and bounds of "biological equivalents".

15. The rejection of claims 5 and 6 are rejected under 35 U.S.C. §112 ¶2 is hereby maintained.

Summary

16. Claims **1, 2, 4-6, 14, 15, 17**, and **29-36** are hereby rejected.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
December 1, 2003

Gary J. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600